

REMARKS OF
HENRY A. WAXMAN,
CHAIRMAN,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
BEFORE
THE AMERICAN PHARMACEUTICAL ASSOCIATION
APRIL 26, 1982

I AM PLEASED TO JOIN YOU FOR YOUR ANNUAL MEETING. I'VE WORKED WITH YOUR ORGANIZATION MANY TIMES IN THE PAST AND IT'S A PLEASURE TO BE ABLE TO SPEAK AT YOUR LEADERSHIP MEETING.

I AM ESPECIALLY INTERESTED IN TALKING AND MEETING WITH YOU NOW, SINCE A RECENT GALLUP POLL HAS SHOWN THAT AMERICANS BELIEVE THAT PHARMACISTS ARE SECOND ONLY TO CLERGYMEN IN THEIR HONESTY AND ETHICAL STANDARDS. CONGRESSMEN AND LAWYERS WERE A LONG WAY DOWN THE LIST, WITH ONLY HALF THE DEGREE OF TRUST THAT PHARMACISTS HAD.

SINCE CLERGYMEN DON'T USUALLY HOLD THEIR CONVENTIONS IN LAS VEGAS, THIS SEEMED THE BEST WAY TO ENJOY A MEETING WITH THE PEOPLE THAT HAVE THE NATION'S CONFIDENCE.

THEN I HAVE TO GO BACK TO WASHINGTON.

I'M AFRAID THAT WASHINGTON DOESN'T ENJOY MUCH OF THE NATION'S
CONFIDENCE THESE DAYS.

THE REAGAN ADMINISTRATION CAME IN PROMISING LOWER DEFICITS, A
BOOMING ECONOMY, AND A SAFETY NET TO TAKE CARE OF THOSE PEOPLE NOT
SERVED BY THEIR MARKETPLACE PLANS.

BUT NOW WASHINGTON AND THE REST OF THE COUNTRY ARE FILLED WITH
BAD NUMBERS, FAKE FORECASTS, TROJAN HORSES, AND A LOT OF BROKEN
PROMISES:

*THE PRESIDENT HAS SAID THAT HE'S HURT THAT NEWSPAPERS WROTE
ABOUT HIS CUTS IN THE CHILDHOOD IMMUNIZATION PROGRAM, BUT
HE CAN'T DENY THAT THERE WILL BE FIVE MILLION FEWER DOSES
OF POLIO AND MEASLES VACCINE AVAILABLE THIS YEAR.

*THE ADMINISTRATION HAS PROMISED THAT WE CAN CONTROL THE
INCREDIBLE GROWTH IN HOSPITAL COSTS THROUGH THE MAGIC OF
COMPETITION, BUT THEY HAVE YET TO MAKE A REAL PROPOSAL TO
DO ANYTHING BUT CUT AND RESTRICT CARE.

*AND THE SO-CALLED "SAFETY NET" IS UNRAVELLING FAST AS THE WHITE
HOUSE PROPOSES CUTS IN SOCIAL SECURITY AND MORE CUTS IN
EDUCATION AND MEDICARE AND MEDICAID.

ALL OF THIS IS ALARMING, BUT IT IS FAMILIAR BY NOW. BEFORE I
DISCUSS THE LEGISLATION OF THIS YEAR, LET ME TRY TO DESCRIBE WHAT
HAPPENED LAST YEAR AS PART OF THE BUDGET PROCESS.

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AS YOU KNOW, MR. STOCKMAN PROPOSED THAT WE CAP MEDICAID AND CUT
IT BY OVER TWO BILLION DOLLARS. THE CONGRESS FORTUNATELY DID NOT
ADOPT THOSE NUMBERS, BUT MY SUBCOMMITTEE, AS WELL AS OUR COUNTERPARTS
ON THE SENATE SIDE, WERE INSTRUCTED TO REDUCE THE PROGRAM BY \$950
MILLION IN 1982. IF WE REFUSED TO MAKE THE REDUCTIONS, THE HOUSE AND
SENATE BUDGET COMMITTEES WOULD COME IN AND DO IT FOR US, WITHOUT
REGARD TO HOW THE CUTS MIGHT AFFECT PROVIDERS AND THE POOR.

ALTHOUGH I HAD OPPOSED ANY REDUCTIONS, I HAD NO CHOICE BUT TO
MAKE THEM IF THE INTEGRITY OF THE MEDICAID PROGRAM WAS TO BE
PRESERVED. WITH THE SUPPORT OF THE FULL COMMITTEE CHAIRMAN, I PUT
TOGETHER A PACKAGE THAT CUT THE REQUIRED AMOUNTS BUT CONTAINED THE
DAMAGE TO THE PROGRAM.

THE THREE MAIN COMPONENTS OF THAT PACKAGE WERE:

1) A PERCENTAGE REDUCTION IN FEDERAL MEDICAID MATCHING
PAYMENTS TO STATES;

2) A CHANGE IN HOSPITAL REIMBURSEMENT RULES; AND OF
PARTICULAR INTEREST TO YOU AS PHARMACISTS,

3) A PROVISION AUTHORIZING THE STATES TO PURCHASE
LABORATORY SERVICES, MEDICAL DEVICES, AND DRUGS THROUGH A
COMPETITIVE BIDDING PROCESS. THIS PROVISION WOULD HAVE ENABLED
STATES TO LIMIT THE "FREEDOM OF CHOICE" WITH RESPECT TO THESE
SERVICES.

THE SENATE FINANCE COMMITTEE, WHICH HAS JURISDICTION OVER MEDICAID, TOOK A DIFFERENT APPROACH. THEY CHOSE TO CAP THE PROGRAM AT AN ARBITRARY LEVEL, TO REDUCE FEDERAL MATCHING RATES, AND TO ELIMINATE "FREEDOM OF CHOICE" ENTIRELY. UNDER THE SENATE PROPOSAL, THE STATES WOULD HAVE BEEN AUTHORIZED TO ENTER INTO "COST EFFECTIVE ARRANGEMENTS" FOR THE PURCHASE OF ANY SERVICES--INCLUDING DRUGS.

FROM MY STANDPOINT, THIS OPENED UP THE POSSIBILITY OF A FORMAL TWO-CLASS SYSTEM OF MEDICAL CARE--ONE FOR THE POOR AND ANOTHER, BETTER ONE FOR EVERYONE ELSE. I OPPOSED SUCH A DOUBLE STANDARD OF HEALTH CARE, AND INDEED BEGAN TO RE-EXAMINE THE HOUSE BILL'S PROVISIONS ABOUT COMPETITIVE BIDDING.

BUT THERE WAS NOT MUCH OF A CHANCE FOR THE CAREFUL EXAMINATION WHICH WE MIGHT NORMALLY GIVE SUCH A CHANGE. WE HAD NO HEARINGS ON THE BILLS. THERE WAS NOT REALLY A SPECIFIC VOTE OR DEBATE ON THE FLOOR OF THE HOUSE. THE REAGAN BUDGET BILL MOVED TOO QUICKLY FOR CONGRESSMEN AND SENATORS TO FOLLOW ANY CHANGES EXCEPT THE ONES THEY HAD WRITTEN.

THE CONFERENCE TO RESOLVE THE DIFFERENCES BETWEEN THE HOUSE AND THE SENATE VERSIONS OF THE BUDGET BILL WAS A HUGE AND UNPRECEDENTED AFFAIR: 58 SUBCONFERENCES WERE MEETING SIMULTANEOUSLY. AS CHAIR OF THE HEALTH AND ENVIRONMENT SUBCOMMITTEE, I WAS NEGOTIATING IN FOUR SEPARATE SUBCONFERENCES.

THE MEDICAID ISSUES WERE ARGUED OUT BETWEEN MY COMMITTEE AND THE SENATE FINANCE COMMITTEE, LED BY SENATOR DOLE. THE NEGOTIATIONS BEGAN ON JULY 15. BY JULY 28, MOST OF THE OTHER SUBCONFERENCES HAD REACHED AGREEMENT, AND THE PRESSURE NOT TO "HOLD UP THE PRESIDENT'S BUDGET BILL" WAS GROWING INTENSE. BUT SENATOR DOLE WAS DUTIFULLY PRESSING THE ADMINISTRATION'S PROPOSALS TO CAP MEDICAID AND REPEAL "FREEDOM OF CHOICE" AND OUR SUBCONFERENCE WAS STILL DEADLOCKED.

BY LATE AFTERNOON IT WAS CLEAR THAT NEITHER SIDE WAS WILLING TO CHANGE THEIR MINDS IN A SMALL CROWDED ROOM IN THE CAPITOL BUILDING. SENATOR DOLE SUGGESTED THAT WE MOVE TO THE SENATE MAJORITY LEADER'S OFFICES, WHERE WE WERE JOINED BY SENATOR BAKER, SENATOR DOMENICI, AND CONGRESSMAN PANETTA OF THE HOUSE BUDGET COMMITTEE.

LATE IN THE EVENING, THE OUTLINE OF A COMPROMISE BEGAN TO EMERGE: FEDERAL MATCHING PAYMENTS WOULD BE REDUCED. HOSPITAL REIMBURSEMENT RATES WOULD BE CHANGED. AND "FREEDOM OF CHOICE" WOULD NOT BE REPEALED, ALTHOUGH THE STATES WOULD BE ALLOWED TO APPLY FOR LIMITED WAIVERS FROM THE SECRETARY.

BUT THE ISSUE OF COMPETITIVE BIDDING REMAINED. WITHOUT THE BENEFIT OF HEARINGS, THE CONTROVERSY WAS AT FIRST UNCLEAR AND THE PROBLEMS CONFUSED. FORTUNATELY I HAD THE BENEFIT OF A GREAT DEAL OF ADDITIONAL INFORMATION FROM PHARMACISTS AND THE PHARMACEUTICAL INDUSTRY, INFORMATION THAT PERSUADED ME THAT THE PURCHASE OF DRUGS THROUGH COMPETITIVE BIDDING WAS NOT SOUND POLICY.

I RAISED THIS AS ONE OF THE LAST MATTERS BEFORE THE MEDICAID SUBCONFERENCE AND THE COMPETITIVE BIDDING PROVISIONS WERE AMENDED TO EXCLUDE DRUGS.

I HOPE THAT SUCH A STEAMROLLER PROCESS WILL NEVER MAKE HEALTH POLICY AGAIN. IT WAS A BAD PROCESS, AND WHILE THE COMPETITIVE BIDDING PROVISIONS WERE WORKED OUT, MANY OTHER DECISIONS WERE FORCED ON THE BASIS OF NUMBERS AND STATISTICS AND NOT WITH ANY FULL UNDERSTANDING OF THE IMPLICATIONS FOR THE STATES OR FOR THE ELDERLY AND MOTHERS AND CHILDREN. ONLY NOW ARE WE BEGINNING TO SEE THE RESULTS.

BUT EVEN BEFORE THOSE RESULTS CAN BE REPORTED, THE WHITE HOUSE HAS PROPOSED A SECOND ROUND OF DEEPER CUTS, AGAIN ASKING THAT SUCH IMPORTANT PUBLIC HEALTH PROGRAMS AS FAMILY PLANNING AND COMMUNITY HEALTH CENTERS BE ELIMINATED ALTOGETHER AND THAT THE MEDICAID PROGRAM BE CUT BY OVER TWO BILLION DOLLARS

IT MIGHT BE USEFUL TO LOOK AT SOME OF THE SPECIFIC ADMINISTRATION PROPOSALS TO SEE JUST WHAT THE MAGNITUDE OF THE MEDICAID COST-SHIFTING WILL BE. THE ADMINISTRATION PROPOSES TO SAVE \$600 MILLION IN FY 1983 BY REDUCING THE CURRENT FEDERAL MEDICAID MATCHING RATE FOR ALL SO-CALLED "OPTIONAL" SERVICES AND "OPTIONAL" ELIGIBILITY GROUPS BY THREE PERCENTAGE POINTS. THIS MEANS STATES WILL EITHER HAVE TO INCREASE THE AMOUNT OF MONEY THEY PUT INTO THE MEDICAID PROGRAM OR CUT BACK ON CURRENT COVERAGE.

LET US BE CLEAR ABOUT WHO THESE "OPTIONAL" GROUPS ARE AND WHAT THESE "OPTIONAL" SERVICES ARE. THE "OPTIONAL" ELIGIBILITY GROUPS ARE NOT JUST THE MEDICALLY NEEDY, BUT ALSO INCLUDE ALL ELDERLY AND DISABLED PERSONS IN NURSING HOMES WITH INCOME IN EXCESS OF \$25 A MONTH.

MOST PEOPLE BELIEVE THAT MEDICARE WILL TAKE CARE OF THEM WHEN THEY BECOME OLD AND FRAIL AND NEED NURSING HOME CARE.

THAT'S NOT TRUE.

ONLY AFTER THEY HAVE EXHAUSTED ALL OF THEIR RESOURCES WOULD THEY BE ELIGIBLE FOR MEDICAID--THE HEALTH CARE PROGRAM FOR THE POOR, AND THEY WOULD BE CONSIDERED A "MANDATORY" ELIGIBLE GROUP ONLY IF THEY HAVE LESS THAN \$25 PER MONTH IN INCOME FROM ALL SOURCES, INCLUDING HELP FROM THEIR CHILDREN. THESE ARE THE FOLKS WHO REAGAN DEFINES AS "OPTIONAL" FOR THE PURPOSE OF CUTTING FEDERAL FUNDS FOR MEDICAID. STATES WOULD HAVE THEIR FEDERAL SUPPORT SLASHED FOR THE LARGE MAJORITY OF MEDICAID AGED AND DISABLED PERSONS IN NURSING HOMES.

THE "OPTIONAL" SERVICES INCLUDE PRESCRIPTION DRUGS, NONSKILLED NURSING HOME CARE, DENTAL CARE, EYEGLASSES, AND HEARING AIDS. THE THREE PERCENTAGE POINT CUT IN FEDERAL MATCHING PAYMENTS WILL FORCE STATES EITHER TO FIND ADDITIONAL FUNDS OF THEIR OWN TO MAKE UP THE SHORTFALL OR TO ELIMINATE COVERAGE FOR THESE SERVICES OR PEOPLE. AND REMEMBER, WE HAVE ALREADY PASSED A FOUR PERCENT PRO RATA CUT IN FEDERAL MATCHING PAYMENTS WHICH WILL GO INTO EFFECT IN FY 1983. SO THE STATES WILL HAVE TO MAKE UP BOTH REDUCTIONS.

YOU SHOULD ALSO KNOW THAT THE WHITE HOUSE IS PROPOSING TO REMOVE ALL LIMITS ON MEDICAID CO-PAYMENTS. THIS CHANGE WOULD ALLOW STATES TO FORCE MEDICAID BENEFICIARIES TO PAY FEES OF ANY SIZE ON PRESCRIPTION DRUGS, NOT JUST THE "NOMINAL" CO-PAYMENT THAT MAY BE REQUIRED NOW. IF HIGH CO-PAYMENTS ARE SET, YOU AS PHARMACISTS WILL BE THE ONES WHO WILL HAVE TO DECIDE WHETHER TO ACCEPT BAD DEBTS FROM POOR PATIENTS OR TO DISCONTINUE SERVICES TO THEM.

I HAVE A CLEAR SENSE THAT THIS ADMINISTRATION FEELS NO NATIONAL RESPONSIBILITY TO PROVIDE CARE OR COVERAGE WHERE THE COMPETITIVE MARKET FAILS.

THE ADMINISTRATION BELIEVES INSTEAD THAT SUCH CARE IS NOT A RIGHT OF AMERICANS, BUT MAYBE ONLY OF CALIFORNIANS OR NEW YORKERS OR THOSE WHO ARE FORTUNATE ENOUGH TO BE OLD IN A WEALTHY AND COMPASSIONATE STATE.

TODAY THAT SHIFT FROM FEDERAL RESPONSIBILITY AFFECTS BLOCK GRANTS FOR HEALTH AND LARGE PARTS OF THE MEDICAID PROGRAM.

THE SO-CALLED "NEW FEDERALISM" IS MUCH THE SAME THING. THE ADMINISTRATION HAS PROPOSED TO TAKE OVER RESPONSIBILITY FOR THE MEDICAID PROGRAM, BUT WHAT KIND OF PROGRAM DO THEY HAVE IN MIND? A PROGRAM THAT PROVIDES ADEQUATE COVERAGE TO THE POOR? OR THE REMAINS OF A PROGRAM DECIMATED BY THE ADMINISTRATION'S BUDGET CUTS? I FEAR THAT WHAT THE ADMINISTRATION REALLY HAS IN MIND IS TO LIMIT FEDERAL DOLLARS FOR HEALTH CARE TO THE POOR, LEAVING THE STATES AND COUNTIES TO BEAR ANY ADDITIONAL COSTS.

IF A VOUCHER SYSTEM FOR MEDICARE BECOMES A REALISTIC PROPOSAL, THE SHIFT AWAY FROM FEDERAL RESPONSIBILITY WILL BECOME EVEN MORE DRAMATIC. THE FEDERAL CONTRIBUTION TO THE CARE OF THE ELDERLY AND DISABLED WILL BE FIXED, AND THESE PATIENTS--AND THEIR PROVIDERS--WILL HAVE TO ABSORB ANY ADDITIONAL EXPENSES.

AND IF STRAIGHTFORWARD CAPS ON MEDICARE AND MEDICAID WERE TO RE-APPEAR--AND THERE IS EVERY INDICATION THAT SOME SENATE REPUBLICANS WILL BE TRYING AGAIN--GOVERNMENTS WOULD HAVE TO CHOOSE AMONG CURRENTLY COVERED SERVICES, TO FIND THE ONES TO CUT. WE CAN IMAGINE THAT "OPTIONAL SERVICES", LIKE PRESCRIPTION DRUGS, WOULD GO FIRST. WE CAN PREDICT THAT NO MEDICALLY NEEDY PERSONS WOULD BE ELIGIBLE.

MAKE NO MISTAKE ABOUT IT. IF THESE NEW PROPOSALS ARE ADOPTED, MILLIONS WILL SUFFER, AND THERE WILL BE NO SAFETY NET TO CATCH THEM. THE MOST VULNERABLE WILL BE REDUCED TO A QUALITY OF LIFE WHICH IS DIFFICULT TO IMAGINE, AND IMPOSSIBLE TO ACCEPT.

I WILL OPPOSE THESE AND ALMOST ALL OF MR. STOCKMAN'S OTHER SHORT-SIGHTED PROPOSALS FOR REDUCING HEALTH CARE. I LOOK FORWARD TO WORKING WITH YOU IN THE FUTURE AS I AM WORKING WITH YOU NOW TO PROVIDE THE HIGHEST QUALITY CARE TO ALL AMERICANS.

ONE OF THOSE AREAS ON WHICH I AM WORKING WITH YOU TODAY IS MORE HOPEFUL THAN THE BUDGET NEGOTIATIONS--ORPHAN DRUGS.

THERE ARE MILLIONS OF PEOPLE IN THIS COUNTRY WHO SUFFER FROM RARE DISEASES. FOR MANY, EFFECTIVE TREATMENT IS NOT YET KNOWN. FOR A GREAT MANY OTHERS, TREATMENTS ARE KNOWN BUT NOT AVAILABLE.

WITH DRUGS FOR RARE DISEASES, OUR PRIVATE DRUG DEVELOPMENT SYSTEM HAS FAILED US. THERE ARE NO INCENTIVES FOR DRUG COMPANIES TO PRODUCE ORPHAN DRUGS, BUT THE SUFFERING OF VICTIMS OF RARE DISEASES IS NOT LESS BECAUSE THEY ARE SO FEW.

IT IS AN UNACCEPTABLE STATE OF AFFAIRS WHEN PEOPLE ARE ALLOWED TO SUFFER BECAUSE THEIR ILLNESS IS NOT PROFITABLE. NO ONE QUESTIONS THE RIGHT OF THE PHARMACEUTICAL INDUSTRY TO MAKE MONEY.

BUT WE COULD AND SHOULD ASK WHETHER THOSE WHO PROFIT FROM THE ILLNESS OF OTHERS DO NOT ALSO HAVE A PUBLIC RESPONSIBILITY TO DO SOMETHING MORE THAN DEVELOP ANOTHER SLEEPING PILL.

IN HEARINGS BEFORE MY SUBCOMMITTEE, MEMBERS OF THE PHARMACEUTICAL INDUSTRY HAVE DESCRIBED REGULATORY BARRIERS TO THE DEVELOPMENT OF ORPHAN DRUGS. I HAVE INTRODUCED A BILL WHICH EASES THESE BARRIERS AND PROVIDES FINANCIAL INCENTIVES TO THE INDUSTRY. THAT BILL NOW HAS 167 CO-SPONSORS.

IN MEETING AND TALKING WITH REPRESENTATIVES OF YOUR PROFESSIONAL ASSOCIATION, I HAVE BECOME AWARE THAT THE BILL AS IT WAS INTRODUCED IS TOO RESTRICTIVE IN THE DISTRIBUTION OF ORPHAN DRUGS AND THAT THERE IS CONCERN THAT WE INTEND TO LIMIT THE DISTRIBUTION TO MEDICAL DOCTORS.

I MUST SAY CLEARLY NOW THAT SUCH WAS NOT MY INTENT.

MY PURPOSE IN INTRODUCING THE ORPHAN DRUG BILL WAS SIMPLY TO GET THESE DRUGS OUT TO PATIENTS WHO NEED THEM, BY WHATEVER DIRECT AND RESPONSIBLE MEANS ARE POSSIBLE.

SINCE I CAN ASSURE YOU THAT I HAVE EVERY BIT AS MUCH CONFIDENCE IN THE HONESTY AND ETHICS OF YOUR PROFESSION AS MR. GALLUP REPORTS THE AMERICAN PEOPLE DO, I CAN ALSO TELL YOU THAT I WILL WORK TO CHANGE WHATEVER PROVISIONS OF MY BILL RESTRICT THE DISPENSING OF THESE SPECIAL DRUGS BY QUALIFIED PHARMACISTS.

BUT I MUST ALSO TELL YOU THAT MY BILL DOES NOT SOLVE THE PROBLEM OF ORPHAN DISEASES AND ORPHAN DRUGS. WHATEVER THE CONGRESS MAY DO, THE DEVELOPMENT AND MANUFACTURE OF MOST OF THESE PHARMACEUTICALS WILL STILL BE UNPROFITABLE. AND DESPITE NUMEROUS MEETINGS WITH THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION, WE STILL DO NOT HAVE A STATEMENT ON THE BILL FROM PMA OR THE COMPANIES THEMSELVES.

TO MEET THE NATIONAL NEED PRESENTED BY ORPHAN DRUGS, THE MANUFACTURERS, THE PHARMACISTS, THE PUBLIC, AND THE GOVERNMENT WILL HAVE TO MAKE A COMMITMENT TO POOL RESOURCES TO CARE FOR VICTIMS OF RARE DISEASES. IF, WITH BROAD SUPPORT AND THE INCENTIVES OF THE BILL, THE INDUSTRY DOES NOT MEET THE CHALLENGE OF DEVELOPING AND MARKETING MORE ORPHAN DRUGS, THEY WILL BE DOING THE AMERICAN PEOPLE A GRAVE DISSERVICE THAT NEITHER THE CONGRESS NOR THE PUBLIC CAN ACCEPT.

THANK YOU FOR INVITING ME TO BE HERE. I LOOK FORWARD TO WORKING WITH YOU IN THE FUTURE AND I WILL BE GLAD TO ANSWER ANY QUESTIONS YOU MAY HAVE NOW.